RESPONSE

I. Restriction Requirement

The Examiner has determined that the original claims are directed to three separate and distinct inventions under 35 U.S.C. § 121, as follows:

Group I: Claims 1-3, said to be drawn to an isolated nucleic acid molecule of SEQ ID NO:1, or that encodes SEQ ID NO:2, classified in class 536, subclass 23.5;

Group II: Claim 4, said to be drawn to an isolated nucleic acid molecule that encodes SEQ ID NO:4, classified in class 536, subclass 23.5; and

Group III: Claim 5, said to be drawn to an isolated nucleic acid molecule that encodes SEQ ID NO:24, classified in class 536, subclass 23.5.

II. Response to Restriction Requirement

In response to the Restriction Requirement, Applicants hereby confirm the election without traverse, made by Applicants' representative David W. Hibler during a telephone conference with the Examiner on February 8, 2002, to prosecute the claims of the Group I invention (Claims 1-3), drawn to an isolated nucleic acid molecule of SEQ ID NO:1, or that encodes SEQ ID NO:2, classified in class 536, subclass 23.5. Accordingly, claims 4 and 5 were canceled without prejudice and without disclaimer by the Examiner under 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions, and this cancellation of claims 4 and 5 has been confirmed by Applicants herein.

Applicants reserve the right to refile claims to the non-elected inventions in one or more future applications retaining the priority date of the present case and the earlier cited priority applications.

III. Status of the Claims

Claims 4 and 5 have been canceled without prejudice and without disclaimer as drawn to non-elected inventions. Claims 1 and 2 have been amended. New claims 6-8 have been added.

Claims 1-3 and 6-8 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as **Exhibit B**.

IV. Support for the Amendments and Newly Added Claims

The specification has been amended to include a new title that is more descriptive of the invention to which the claims are directed. Support for the new title can be found in the original title, and throughout the specification and claims as originally filed. In compliance with 37 C.F.R. § 1.121(b)(1)(iii), a marked up copy of the original title is attached hereto as **Exhibit C**.

Claim 1 has been amended to further clarify the claim, and to recite that the isolated nucleic acid molecule comprises the nucleotide sequence of SEQ ID NO:1. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in claim 1 as originally filed and in Section 5.1.

Claim 2 has been amended to further clarify the claim, and to recite specific highly stringent hybridization conditions. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 4, lines 2-5.

Claims 6 and 7 have been added to specifically recite recombinant expression vectors comprising isolated nucleic acid molecules of the present invention. Support for these claims can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 4-10.

Claim 8 has been added to specifically recite host cells comprising the recombinant expression vectors of claim 6. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 10-16.

It will be understood that no new matter is included within the new title, or the amended or newly added claims.

V. Information Disclosure Statement

The Action notes that the first Information Disclosure Statement (IDS), submitted by Applicants on August 30, 2001, was not received by the Patent and Trademark Office. However, during a telephone conference between Examiner Landsman and Applicants' representative David W. Hibler on May 20, 2002, it was confirmed by Examiner Landsman that the first Information Disclosure Statement, submitted by Applicants on August 30, 2001, had indeed been received by the Patent and Trademark Office. Therefore, a substitute IDS does not need to be submitted by Applicants.

VI. Oath/Declaration

The Action notes that the declaration is defective because the signature of Frank Wattler does not match the full printed name. Applicants submit herewith a supplemental declaration in compliance with 37 C.F.R. § 1.67(a), which identifies the application by application number and filing date.

VII. Title

The Action next objects to the title of the application as being non-descriptive. Applicants have amended the title of the present application to more accurately reflect the currently pending claims. In compliance with 37 C.F.R. § 1.121(b)(1)(iii), a marked up copy of the original title is attached hereto as **Exhibit C**.

Applicants request that, since the objection has been overcome, this objection be withdrawn.

VIII. Abstract

The Action next objects to the abstract of the application as being non-descriptive. Applicants point out that numerous issued U.S. Patents have an abstract **identical** to the present abstract. Specifically, Applicants direct the Examiner's attention to issued U.S. Patent Nos. 6,433,153, 6,441,153, 6,441,154, 6,444,456 and 6,448,388. As issued U.S. Patents are presumed to meet all necessary PTO requirements, Applicants submit that the present abstract must also meet all necessary PTO requirements.

Applicants request that, since the objection has been overcome, this objection be withdrawn.

IX. Objections

The Action objects to the terms "first described in" in claim 1, and "shown in" in claim 2. Solely in order to progress the case more rapidly to allowance, Applicants have removed these terms from claims 1 and 2, respectively. Applicants state for the record that these amendments in no way limit claims 1 and 2 in relation to their original scope.

Applicants request that, since these objections have been overcome, these objections be withdrawn.

X. Rejection of Claims 1-3 Under 35 U.S.C. § 101

The Action first rejects claims 1-4 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

The present invention has a number of substantial and credible utilities, not the least of which is in diagnostic assays, as described in the specification, at least at page 10, lines 15-19. As described in the specification at page 15, lines 21-25, the present sequences define a coding single nucleotide polymorphism - specifically, a C/T polymorphism at position 812 of SEQ ID NO:1, which can lead to a serine or leucine residue at amino acid position 271 of SEQ ID NO:2. As such polymorphisms are the basis for diagnostic assays such as forensic analysis, which is undoubtedly a "real world" utility, the present sequences must in themselves be useful. It is important to note that the presence of more useful polymorphic markers for forensic analysis would not mean that the present sequences lack utility.

The Examiner states that the specification does not "disclose a specific and substantial biological role" for the claimed sequences (Action at page 4). Applicants disagree, as the presently claimed sequence is clearly referred to as a neurexin-like protein (see, at least, the specification at page 1, lines 9-12, and page 2, lines 1-3), and further, that neurexins "mediat(e) neural processes" (specification at page 1, lines 24-25). Furthermore, Applicants would like to invite the Examiner's attention to the fact that two sequences sharing nearly 100% percent identity at the protein level with the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank), and have been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens caspr5 protein" (GenBank accession numbers NM_130773 (**Exhibit D**) and AB077881 (**Exhibit E**)). It is well-known in the art that caspr proteins are members of the neurexin superfamily. The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given these GenBank annotations, there can be no question that those skilled in the art would clearly believe that Applicants' sequence is a neurexin-like protein.

Applicants also point out for the record that the association between neurexins and a variety of neural processes has long been recognized by skilled artisans, as evidenced by a steady stream of scientific manuscripts describing the these relationships, for example, see: Einheber *et al.*, 1997, J. Cell Biol. 139:1495-1506; Bellen *et al.*, 1998, Trends Neurosci. 21:444-449; Poliak *et al.*, 1999, Neuron

24:1037-1047; Rios *et al.*, 2000, J. Neurosci. 20:8354-8364; Poliak *et al.*, 2001, J. Neurosci. 21:7568-7575; Gollian *et al.*, 2002, J. Cell Biol. 157:1247-1256; and Spiegel *et al.*, 2002, Mol. Cell. Neurosci. 20:283-297 (abstracts presented in **Exhibit F**). Thus, neurexins, such as the presently described protein, have a well-established utility. As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988). The present specification also teaches that neurexins are associated with mediating neural processes (specification at page 1, lines 24-25). Thus, the skilled artisan would readily appreciate the utility associated with the provision of a novel human neurexin-like protein sequence, and therefore, the present utility rejection must fail.

The Action cites an article by Skolnick *et al.* ("Skolnick"; 2000, Trends in Biotech. 18:34-39) for the proposition that "(k)nowing the protein structure by itself is insufficient to annotate a number of functional classes and is also insufficient for annotating the specific details of protein function" (Skolnick at page 36, emphasis added). However, Skolnick concerns predicting protein function not by overall amino acid homology to other family members, but instead concerns prediction of function based on the presence of certain functional "motifs" present within a given protein sequence. Thus, Skolnick does not apply to the current situation, where overall protein homology is used to assign function to a particular sequence. However, even in the event that Skolnick is applicable, Skolnick itself concludes that "sequence-based approaches to protein-function prediction have proved to be very useful" (Skolnick at page 37), admitting that such methods have correctly assigned function in 50-70% of the cases, thus arguing against the conclusion drawn in the Action.

The Examiner next cites Bork (Genome Research *10*:398-400, 2000) as supporting the proposition that prediction of protein function from homology information is somewhat unpredictable. However, nowhere in Bork is there a comparison of the prediction accuracy based on the percentage homology between two proteins or two classes of proteins, and thus does not support the alleged lack of utility for the present invention. Additionally, Bork concludes that "there is still no doubt that sequence analysis is extremely powerful" (Bork at page 400), also arguing against the conclusion drawn in the Action.

The Examiner next cites Doerks *et al.* (Trends in Genetics *14*:248-250, 1998) for the proposition that sequence-to-function methods of assigning protein function are prone to errors.

However, Doerks *et al.* states that "utilization of family information and thus a more detailed characterization" should lead to "simplification of update procedures for the entire families if functional information becomes available for at least one member" (Doerks *et al.*, page 248, paragraph bridging columns 1 and 2, emphasis added). Applicants point out that, as detailed above, two sequences sharing nearly 100% percent identity at the protein level with the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank), and have been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens caspr5 protein" (GenBank accession numbers NM_130773 (**Exhibit D**) and AB077881 (**Exhibit E**)). The neurexin superfamily is a well-studied protein family with a large amount of known functional information, exactly the situation that Doerks *et al.* suggests will "simplify" and "avoid the pitfalls" of previous sequence-to-function methods of assigning protein function (Doerks *et al.*, page 248, columns 1 and 2). Thus, instead of supporting the Examiner's position against utility, Doerks *et al.* actually supports Applicants' position that the presently claimed sequences have a substantial and credible utility.

The Examiner next cites Smith *et al.* (Nature Biotechnology *15*:1222-1223, 1997) as teaching "that there are numerous cases in which proteins of very different functions are homologous" (Action at page 6). However, the Smith and Zhang article also states "the major problems associated with nearly all of the current automated annotation approaches are - paradoxically - minor database annotation inconsistencies (and a few outright errors)" (page 1222, second column, first paragraph, emphasis added). Thus, Smith and Zhang do not in fact seem to stand for the proposition that prediction of function based on homology is fraught with uncertainty, and thus also does not support the alleged lack of utility. The citation of Pilbeam *et al.* ("Pilbeam"; 1993, Bone 14:717-720), which allegedly details that "PTH and PTHrP are two structurally closely related proteins which can have opposite effects on bone resorption" (Action at page 6), is also hardly indicative of a high level of uncertainty in assigning function based on sequence. In fact, Pilbeam details that "the biological activities of hPTHrP 1-34 and synthetic bPTH 1-34 have generally been shown to be qualitatively similar" (Pilbeam at page 717), and thus also does not support the alleged lack of utility.

The Examiner next cites Brenner (TIG *15*:132-133, 1999) as teaching that "most homologs must have different molecular and cellular functions" (Action at page 6). However, this statement is based on the assumption that "if there are only 1000 superfamilies in nature, then most homologs must

have different molecular and cellular functions" (Brenner, page 132, second column). Furthermore, Brenner suggests that one of the main problems in using homology to predict function is "an issue solvable by appropriate use of modern and accurate sequence comparison procedures" (Brenner, page 132, second column), and in fact references an article by Altschul *et al.*, which is the basis for one of the "modern and accurate sequence comparison procedures" used by Applicants. Thus, the Brenner article also does not support the alleged lack of utility.

The Examiner finally cites Bork *et al.* (Trends in Genetics *12*:425-427, 1996) as supporting the proposition that prediction of protein function from homology information is somewhat unpredictable, based on the "structural similarity of a small domain of the new protein to a small domain of a known protein" (Action at page 3). Thus, the Examiner's reliance on Bork *et al.* has the same failing as described above for Doerks *et al.*, specifically, the assumption that Applicants assertion that the present sequences are transporter proteins are made on the basis of structural similarity of a small domain of the new protein to a small domain of a known protein. Applicants again would like to invite the Examiner's attention to the fact that two sequences sharing nearly 100% percent identity at the protein level with the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank), and have been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens caspr5 protein" (GenBank accession numbers NM_130773 (**Exhibit D**) and AB077881 (**Exhibit E**)). Thus, Applicants assertion that the present sequences are neurexin-like proteins are not made on the basis of "structural similarity of a small domain of the new protein to a small domain of a known protein", but rather vast homology over the entire sequence. Thus, Bork *et al.* also does not support the alleged lack of utility for the present invention.

Rather, as set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed

that "anything under the sun that is made by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

In *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

> At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. <u>This is not a new issue; it is one which we would have thought had been settled by case law years ago</u>.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. The Examiner implies that a "real-world" utility does not require "further characterization" (Action at page 4). However, even if, *arguendo*, further research might be required in certain aspects of the present invention, this does not preclude a finding that the invention has utility, as set forth by the Federal Circuit's holding in *Brana*, which clearly states, as highlighted in the quote above, that "pharmaceutical inventions, necessarily includes the expectation of <u>further research and development</u>" (*Brana* at 1442-1443, emphasis added). In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key

term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

As an additional example of the utility of the present nucleotide sequences, the specification details on page 5, lines 12-14, that the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. Such "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776. As the present sequences are specific markers of the human genome, and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be an ideal, novel candidate for assessing gene expression using such DNA chips. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful.

Evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, two such companies (Agilent acquired by American Home Products and Rosetta acquired by Merck) were viewed to have such "real world" value that they were acquired by large pharmaceutical companies for significant sums of money. The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established. Clearly, persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, *e.g.*, Venter *et al.*, 2001, Science *291*:1304). The results have been a stunning success as the

utility of human genomic data has been widely recognized as a great gift to humanity (see, *e.g.*, Jasny and Kennedy, 2001, Science *291*:1153). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years).

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as a further example of the utility of the presently claimed polynucleotide, as described in the specification at least at page 10, line 18, the present nucleotide sequence has a specific utility in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions. Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. In fact, it is this specificity that makes this particular sequence so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequence.

Finally, the requirements set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the Patent and Trademark Office ("the PTO") itself for compliance with 35 U.S.C. § 101. The PTO has issued numerous patents on polynucleotide sequences that have not been directly shown to be associated with the function of the protein that is set forth in the specification, or a direct association between the claimed sequences and a particular disease or condition (Action at page 6), the conditions apparently set forth by the Examiner as allegedly necessary to comply with 35 U.S.C. § 101. The Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,2812 (each of which claims short polynucleotide fragments), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples). None of these issued U.S. Patents

contain examples of the "real-world" utilities that the Examiner seems to be requiring in the present Action. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section XI below), Applicants submit that the presently claimed polynucleotide must also meet the requirements of 35 U.S.C. § 101.

For each of the foregoing reasons, Applicants submit that as the presently claimed nucleic acid molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1-3 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

XI. Rejection of Claims 1-3 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-3 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-3 have been shown to have "a specific, substantial, and credible utility", as detailed in section X above, the present rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, be withdrawn.

XII. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly not providing enablement for the full scope of the claimed invention comprising a genus of at least 24 contiguous nucleotides of SEQ ID NO:1. While Applicants in no way agree that the present application does not provide enablement for nucleotide sequences comprising at least 24 contiguous nucleotides from SEQ ID NO:1, as claim 1 currently recites only nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO:1, which the Examiner admits is enabled (Action at page 7), the present rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has been rendered moot. Applicants therefore respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, first

paragraph, be withdrawn.

XIII. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Again, while Applicants in no way agree that the present application does not provide sufficient written description for nucleotide sequences comprising at least 24 contiguous nucleotides from SEQ ID NO:1, as claim 1 currently recites only nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO:1, which the Action admits is disclosed in the specification (Action at page 9), the present rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has been rendered moot. Applicants therefore respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, be withdrawn.

XIV. Rejection of Claim 2 Under 35 U.S.C. § 112, Second Paragraph

The Action next variously rejects claim 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Action first rejects claim 2 as allegedly indefinite based on the term "stringent hybridization conditions", because the specific hybridization and washing conditions are not recited in the claim. Applicants stress that "a claim need not 'describe' the invention, such description being the role of the disclosure". *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). However, while Applicants submit that the term is sufficiently definite, as a number of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art, solely in order to progress the case more rapidly toward allowance the claim has been revised to recite specific highly stringent hybridization conditions. As the specification provides specific teaching regarding highly stringent hybridization conditions, at least at page 4, lines 2-5, Applicants submit that revised claim 2 even more clearly meets the requirements of 35 U.S.C. § 112, second paragraph.

The Action next rejects claim 2 because part (b) of the claim is allegedly indefinite. While Applicants believe that claim 2 is sufficiently definite, solely in order to progress the case more rapidly